

EXHIBIT D

EXHIBIT C

**to Ethicon's Response in Opposition to
Plaintiffs' Motion to Exclude Dr. Larry T. Sirls'
TVT/TVT-O General Opinions**

Larry T. Sirls, II, M.D.

1 UNITED STATES DISTRICT COURT
2 SOUTHERN DISTRICT OF WEST VIRGINIA AT CHARLESTON
3 Master File No.
4 2:12-MD-02327

5 IN RE: ETHICON, INC., PELVIC
6 REPAIR SYSTEM PRODUCTS MDL 2327
LIABILITY LITIGATION JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE

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10 The deposition of LARRY T. SIRLS, II, M.D.,
11 Taken at 41000 Woodward Avenue, Suite 200 East,
12 Bloomfield Hills, Michigan,
13 Commencing at 9:33 a.m.,
14 Thursday, July 21, 2016,
15 Before Cheryl McDowell, CSR-2662, RPR.

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<p style="text-align: right;">Page 14</p> <p>1 Doctor Sirls, who put together this</p> <p>2 binder for you?</p> <p>3 A. That binder was put together by Butler Snow.</p> <p>4 Q. Okay. And who chose the articles that went in this</p> <p>5 binder?</p> <p>6 A. I did.</p> <p>7 Q. Okay. And did you communicate to Butler Snow which</p> <p>8 articles you wanted included here?</p> <p>9 A. Yeah. In my report we have these references, but</p> <p>10 then there are additional references that are not in</p> <p>11 my report that are in that folder.</p> <p>12 Q. Okay. Is everything that's in here reflected in</p> <p>13 your reliance list?</p> <p>14 A. Yes.</p> <p>15 Q. Okay.</p> <p>16 A. It should be to the best of my knowledge, it should</p> <p>17 be, yes.</p> <p>18 Q. And in the process of putting together your report</p> <p>19 in this binder, did Butler Snow suggest or direct</p> <p>20 you to any articles that they published for you to</p> <p>21 look at or to include in this binder specifically?</p> <p>22 A. No.</p> <p>23 Q. Looking at Exhibits 4 and 5, those are internal</p> <p>24 Ethicon documents.</p>	<p style="text-align: right;">Page 16</p> <p>1 number of peer-reviewed articles, correct?</p> <p>2 A. Yes.</p> <p>3 Q. And you've published a number of peer-reviewed</p> <p>4 articles on a wide variety of topics, correct?</p> <p>5 A. Mostly pelvic reconstructive surgery.</p> <p>6 Q. Okay. And lots of different subtopics, though,</p> <p>7 within pelvic reconstructive surgery, correct?</p> <p>8 A. Yes.</p> <p>9 Q. And in publishing those articles and prior to</p> <p>10 working as an expert for Ethicon, you've never</p> <p>11 consulted internal industry or company documents for</p> <p>12 any of the academic writings that you personally</p> <p>13 have done, correct?</p> <p>14 A. Prior to receiving these documents, I had not</p> <p>15 reviewed documents like this in my academic work.</p> <p>16 Q. Okay. And when were you provided with these</p> <p>17 documents?</p> <p>18 A. I don't know exactly. Probably seven to nine months</p> <p>19 ago.</p> <p>20 Q. Okay. And who selected these internal documents?</p> <p>21 A. Butler Snow.</p> <p>22 Q. Okay. And Butler Snow gave you a series it looks</p> <p>23 like of about a hundred and fifty or so internal</p> <p>24 Ethicon documents, give or take a few, is that</p>
<p style="text-align: right;">Page 15</p> <p>1 Now, Doctor, you didn't have any access</p> <p>2 to these documents prior to being retained by an</p> <p>3 expert -- as an expert for Ethicon, correct?</p> <p>4 A. Yes, correct.</p> <p>5 Q. Okay. And these are documents that you reviewed in</p> <p>6 connection with your expert report, correct?</p> <p>7 A. These are documents that I reviewed to make me</p> <p>8 understand the process and understand what was going</p> <p>9 on within the company.</p> <p>10 It is not part of my expert report. My</p> <p>11 expert report is based on the literature.</p> <p>12 Q. Okay. And the types of documents that you've given</p> <p>13 me in Exhibits 4 and 5, those are not the types of</p> <p>14 documents that you would customarily rely on to do</p> <p>15 your work in your peer-reviewed publications,</p> <p>16 correct?</p> <p>17 A. These documents inform me, and I find them</p> <p>18 interesting.</p> <p>19 Q. Okay.</p> <p>20 A. It is not something that I use for my report, for my</p> <p>21 expert report.</p> <p>22 Q. Okay. So I'm asking you something that's a little</p> <p>23 bit different.</p> <p>24 You as a clinician and academic publish a</p>	<p style="text-align: right;">Page 17</p> <p>1 correct?</p> <p>2 A. So some of these are internal documents. Some of</p> <p>3 these are federal regulations. Some of these are</p> <p>4 publications or abstracts or discussions. Some of</p> <p>5 these are IFUs.</p> <p>6 So there are a variety of different</p> <p>7 materials in those books.</p> <p>8 Q. Okay. I just want to make sure that I'm</p> <p>9 conceptually getting that right.</p> <p>10 Would it be fair to say that what's in</p> <p>11 Exhibit 8 which are the medical articles, those are</p> <p>12 the medical articles that you personally selected as</p> <p>13 reliance for your report, is that right?</p> <p>14 A. That's part of it, correct.</p> <p>15 Q. Okay. And then what is included in 4 and 5 are</p> <p>16 things that the lawyers for Ethicon gave you to</p> <p>17 review in connection with your expert report, is</p> <p>18 that right?</p> <p>19 A. I want to clarify my earlier answer.</p> <p>20 Q. Sure.</p> <p>21 A. And that is that in this there are IFUs and things</p> <p>22 that I had and was aware of and had read before they</p> <p>23 were given to me.</p> <p>24 Q. Okay.</p>

<p style="text-align: right;">Page 26</p> <p>1 specific last summer, fall, and one for a TVT-O</p> <p>2 specific that we'll discuss today.</p> <p>3 Is that the entire --</p> <p>4 A. To the best of my knowledge, yes.</p> <p>5 Q. Okay. And what did you do to prepare for your</p> <p>6 deposition today?</p> <p>7 A. I reviewed my materials, my report, the binders you</p> <p>8 see in front of me, met with Mr. Koopmann.</p> <p>9 Q. Okay. How many hours did you prepare for your</p> <p>10 deposition?</p> <p>11 A. For the deposition?</p> <p>12 Q. Yes.</p> <p>13 A. Well, I'm probably -- so does that include reviewing</p> <p>14 all of this?</p> <p>15 Q. Uh-huh.</p> <p>16 A. Okay. Include writing up a report?</p> <p>17 Q. No. Anything you've done specifically to prepare</p> <p>18 for sitting here today and answering questions.</p> <p>19 A. Would that include reviewing the documents for the</p> <p>20 case, correct?</p> <p>21 Q. Whatever you did.</p> <p>22 A. So my report, I probably spent close to ninety hours</p> <p>23 on my report.</p> <p>24 Q. Okay.</p>	<p style="text-align: right;">Page 28</p> <p>1 Q. Okay. Now, you did a fellowship with Doctor Zimmern</p> <p>2 in Los Angeles from 1992 to 1993, is that correct?</p> <p>3 A. The lead, the lead physician in the fellowship was</p> <p>4 Gary Leach. Phillippe Zimmern was an associate.</p> <p>5 Q. Okay. And how closely did you work with</p> <p>6 Doctor Zimmern at that time?</p> <p>7 A. Very closely.</p> <p>8 Q. Do you currently have a teaching appointment at any</p> <p>9 educational institution?</p> <p>10 A. I am the fellowship director at Beaumont Health for</p> <p>11 female pelvic medicine and reconstructive surgery.</p> <p>12 I direct urology research for the residency program</p> <p>13 in the same institution. I'm a professor in urology</p> <p>14 at Oakland University William Beaumont School of</p> <p>15 Medicine.</p> <p>16 Q. Okay. And do you currently act as a peer reviewer</p> <p>17 for any medical journal?</p> <p>18 A. Yes.</p> <p>19 Q. And what medical journal is that?</p> <p>20 A. The Journal of Urology, the Urology, Neurourology,</p> <p>21 Urodynamics, Female Pelvic Medicine and</p> <p>22 Reconstructive Surgery.</p> <p>23 Q. Okay. Now, you offer your opinions in this case as</p> <p>24 a clinician and a medical doctor, correct?</p>
<p style="text-align: right;">Page 27</p> <p>1 A. Reviewing additional documents, and I haven't</p> <p>2 tallied up, so I'm giving you a generality.</p> <p>3 Q. Sure.</p> <p>4 A. I could be off a little bit. Reviewing the binders</p> <p>5 that we see in front of us, the literature,</p> <p>6 et cetera, another seventy hours or so. And then</p> <p>7 the case-specific medical records, probably in the</p> <p>8 thirties that I've done with that, and then I've met</p> <p>9 with Mr. Koopmann probably somewhere between fifteen</p> <p>10 and twenty hours.</p> <p>11 Q. Okay. So if I'm doing my math right, it looks like</p> <p>12 you spent anywhere between two hundred and five</p> <p>13 to -- let's say two hundred to two hundred and ten</p> <p>14 hours total drafting your report, doing the</p> <p>15 case-specific report, reviewing your medical</p> <p>16 records, and reviewing the documents for the</p> <p>17 deposition, is that about right?</p> <p>18 A. Somewhere in there.</p> <p>19 Q. Okay. And we've had marked now the most current</p> <p>20 copy of your CV.</p> <p>21 And is this a complete and accurate</p> <p>22 statement of your educational background and your</p> <p>23 training?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 29</p> <p>1 A. Clinician, medical doctor, academician.</p> <p>2 Q. Okay. And it's based largely on your clinical</p> <p>3 experience, correct?</p> <p>4 A. Clinical experience, literature, discussions with</p> <p>5 friends, colleagues, meetings, et cetera.</p> <p>6 Q. And you're not holding yourself out as an expert</p> <p>7 with regard to the material science of</p> <p>8 polypropylene, correct?</p> <p>9 A. I have done a lot of literature review on the</p> <p>10 material science. It's very important in my</p> <p>11 practice because I use these materials, and I would</p> <p>12 say that I am a clinical expert in the use of these</p> <p>13 materials, their outcomes, their complications,</p> <p>14 et cetera.</p> <p>15 Q. Okay. Now, you gave a deposition before, correct?</p> <p>16 A. Yes.</p> <p>17 Q. And have you reviewed that deposition in preparation</p> <p>18 for your deposition here today?</p> <p>19 A. No.</p> <p>20 MS. FITZPATRICK: Okay. So why don't we</p> <p>21 go ahead and mark this as Exhibit 9.</p> <p>22 (Sirls TVT-9 marked and attached.)</p> <p>23 BY MS. FITZPATRICK:</p> <p>24 Q. Go ahead and take a look at that, Doctor. I'd like</p>

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<p>1 you to look at page forty-two, line seven through</p> <p>2 ten.</p> <p>3 And you were asked at that time: You</p> <p>4 don't hold yourself out as an expert with regard to</p> <p>5 material science of polypropylene mesh, is that</p> <p>6 correct? And you answered correct.</p> <p>7 Are you changing your testimony today?</p> <p>8 A. Yes, I am.</p> <p>9 Q. Okay. And tell me what you've done between December</p> <p>10 12th, excuse me, December 14th, 2012, and today that</p> <p>11 changed you from not being an expert about material</p> <p>12 science with regard to polypropylene mesh and to now</p> <p>13 holding yourself out as an expert on that specific</p> <p>14 topic.</p> <p>15 A. So during this deposition, this one that we're</p> <p>16 talking about, it's the first time I've been</p> <p>17 involved in the process like this, and I was naive</p> <p>18 and really did not understand the questions so well.</p> <p>19 In that time it's been three and a half</p> <p>20 years. These products have come under much more</p> <p>21 scrutiny, and I have gone to the literature, talked</p> <p>22 to my friends, et cetera, gone to meetings, and have</p> <p>23 become much more educated with regard to these</p> <p>24 materials.</p>	<p>1 Q. Okay. But I'm not asking you whether you're an</p> <p>2 expert in the use of the products and whether you're</p> <p>3 an expert in the clinical outcomes and implanting</p> <p>4 them in women.</p> <p>5 Maybe let me ask you this. How many</p> <p>6 different kinds of polypropylene are there in the</p> <p>7 world?</p> <p>8 A. So polypropylene is a polymer that I want to make</p> <p>9 sure I understand your question.</p> <p>10 Do you mean how many makers are there?</p> <p>11 Q. How many different types?</p> <p>12 A. I don't understand your question.</p> <p>13 Q. Do you know that there's different grades of</p> <p>14 polypropylene?</p> <p>15 A. What do you mean by different grades?</p> <p>16 Q. This is what I'm actually trying to get at. It</p> <p>17 seems to me from your expert report that you are an</p> <p>18 expert sitting here to tell me about the clinical</p> <p>19 implications and uses of polypropylene mesh</p> <p>20 products, particularly the TVT and the TVT-O, in</p> <p>21 women. That's what I got from your expert report,</p> <p>22 okay?</p> <p>23 What I'm trying to get at is whether you</p> <p>24 are also an expert on the chemical and physical</p>
Page 31	Page 33
<p>1 So I state that I am a clinical expert in</p> <p>2 the use and clinical evaluation and outcomes of</p> <p>3 these products.</p> <p>4 Q. Okay. Well, what I'm trying to get at is I</p> <p>5 understand that you're here as a clinician to talk</p> <p>6 about the use and the medical outcomes that come</p> <p>7 with using specifically the TVT and the TVT-O</p> <p>8 device, correct?</p> <p>9 A. Yes.</p> <p>10 Q. What I'm trying to get at is beyond that, those</p> <p>11 clinical opinions that you hold and that you've</p> <p>12 reported here, do you hold yourself out specifically</p> <p>13 as someone who is an expert in the material of</p> <p>14 polypropylene itself?</p> <p>15 A. I have reviewed thousands of pages of documents in</p> <p>16 preparation, and I have reviewed quite a bit on</p> <p>17 degradation, FDA regulations, preparation,</p> <p>18 et cetera.</p> <p>19 I think that I probably know more about</p> <p>20 the use of these products than many of the engineers</p> <p>21 who write these reports because I'm the one who's</p> <p>22 putting them in patients and evaluating their</p> <p>23 outcomes. So, yeah, I feel I'm extremely well</p> <p>24 versed and expert in using these products.</p>	<p>1 properties of polypropylene, polypropylene material</p> <p>2 generally, not in a clinical setting, but just</p> <p>3 there's people who specialize in polymers and</p> <p>4 plastics.</p> <p>5 Are you one of those people?</p> <p>6 A. I don't specialize in polymers and plastics.</p> <p>7 Q. Okay.</p> <p>8 A. But I'm informed and educated about many of these</p> <p>9 issues with polypropylene materials.</p> <p>10 Q. Okay. Great. Tell me about the different grades of</p> <p>11 polypropylene.</p> <p>12 A. What I can tell you is that prolene mesh is</p> <p>13 different than polypropylene because it's treated,</p> <p>14 right, with antioxidants.</p> <p>15 Q. And what are those antioxidants?</p> <p>16 A. Santanox and DTL-DP.</p> <p>17 Q. And tell me how a manufacturer decides what</p> <p>18 concentration of antioxidants should be used in a</p> <p>19 particular polypropylene product.</p> <p>20 A. I don't know that.</p> <p>21 Q. Okay. Tell me the difference between the</p> <p>22 polypropylene that is used for an Ethicon product</p> <p>23 versus a polypropylene that is used for a Boston</p> <p>24 Scientific product.</p>

<p style="text-align: right;">Page 42</p> <p>1 A. Our hospital has a policy on all material explants, 2 and it goes to the pathology lab and we get a 3 pathology report. They do not study the 4 polypropylene for degradation. 5 Q. Okay. So in your clinical practice, you don't have 6 any experience in reviewing pathology or looking at 7 pathology microscopically for degradation, is that 8 right? 9 A. I have not done it in my clinical practice on 10 materials that I've explanted. 11 Q. Okay. Have you done it in another way in your 12 clinical practice? 13 A. Clinical practice to me means reading the literature 14 and understanding things. So it's just in the 15 literature and discussions. That's where my 16 information's coming from. 17 Q. Maybe this is where we're talking a little past each 18 other. Just by way of shorthand, when I talk about 19 your clinical practice, I'm talking about your 20 actual treatment of women, okay? When we talk about 21 your academic practice, I'm talking about your 22 knowledge of the literature and the articles you 23 write and all of that type of stuff. So I want to 24 focus solely on your clinical practice.</p>	<p style="text-align: right;">Page 44</p> <p>1 clinical experience because they're logical to us, 2 they're intuitive, and we think that it may be an 3 upgrade over what we're doing. 4 For example, I'm starting a study next 5 month where I'll be implanting a device that's never 6 been done before like this, and I'll be the first 7 one doing it. There's no data on that. 8 Q. Okay. Is that part of a clinical trial? 9 A. In that case it will be. 10 Q. Okay. And that's a case where you tell the women or 11 men who are getting this new device that they are 12 part of a clinical trial, correct? 13 A. That is correct. 14 Q. And you'll tell them that they are getting a device 15 that doesn't have an established record of safety, 16 correct? 17 A. That's correct. 18 Q. And you'll tell them they are getting a device that 19 doesn't have an established record of efficacy, 20 correct? 21 A. So let me also back up to your prior question on 22 safety. When we do these, we have typically very 23 similar things that have been done that have been 24 shown to be safe and effective. So we're not going</p>
<p style="text-align: right;">Page 43</p> <p>1 There's nothing in your clinical practice 2 of treating women where you've done anything to 3 specifically look for or study degradation of 4 polypropylene mesh explants, correct? 5 A. Correct. 6 Q. And so your knowledge comes from reading somebody 7 else's articles in the medical and scientific 8 literature, is that right? 9 A. Yes. 10 Q. Okay. You started using the TVT device in 2005, 11 correct? 12 A. Yeah. It may have been 2004. I'm sorry. It's in 13 that time period. 14 Q. Okay. And prior to using a new medical device, you 15 personally as a physician would want to be convinced 16 that the device was safe and effective, correct? 17 A. Yes. 18 Q. Okay. And you wouldn't use personally a medical 19 device that didn't have a proven track record of 20 safety? 21 A. Well, so that's where surgery is a little bit 22 different than, for example, medications that can be 23 powered and randomized in large studies. In surgery 24 we will often do procedures that do not have a large</p>	<p style="text-align: right;">Page 45</p> <p>1 in and doing something that we don't have a concept 2 of safety and efficacy for. 3 Similarly, when we do surgical implants, 4 from my first TVT or my first TOT, they were not in 5 a clinical trial, and I had to tell my patient, 6 look, this is my first one, but this is why I'm 7 doing this, it's logical. 8 Q. And so with your first TVT and TVT-O that you did, 9 prior to implanting those devices, did you do a 10 review of the medical and scientific literature to 11 satisfy yourself that the procedures and the devices 12 were safe? 13 A. Yeah, that's a really good question because, as you 14 know, the procedures were developed in '96, '97, 15 '98, and I did not put my first one until 2004, 16 2005. So I was very cautious and I waited and 17 watched the literature. 18 We're talking about TVT, right? 19 Q. Yes. 20 A. TOT was later, 2001, 2002, 2003. So, you know, I 21 was very cautious and watched the literature. So I 22 did do that exactly before, before I implanted it in 23 my first clinical patient, and I was very 24 comfortable.</p>

<p style="text-align: right;">Page 46</p> <p>1 Q. Okay. So it was important to you that you had 2 scientific data before implanting the TVT device 3 into women, correct?</p> <p>4 A. Again, there are different degrees of comfort and 5 different amounts of data that are necessary before 6 a surgeon feels comfortable doing something.</p> <p>7 But, yeah, typically before I'm going to 8 do it on my patient, I will have some literature, 9 some discussions, some meetings, some information 10 that makes me feel comfortable moving ahead.</p> <p>11 Q. And you did that with the TVT device, right?</p> <p>12 A. I did.</p> <p>13 Q. And you did that with the TVT-O device, right?</p> <p>14 A. I did.</p> <p>15 Q. What literature did you rely on to satisfy yourself 16 that the TVT was safe before you started using it?</p> <p>17 A. The literature that would have been published at 18 that time. I don't recall what was published at 19 that time in that time period. I was watching very 20 actively because I was skeptical, I was very 21 skeptical.</p> <p>22 But, let's see. It was Nilsson, Ulmsten, 23 and then the people in the states. Who were the 24 early TVT people? Maybe Dennis Miller, maybe Vince</p>	<p style="text-align: right;">Page 48</p> <p>1 prior to implanting your first TVT?</p> <p>2 A. So what the information I probably would have 3 received from Ethicon at that time would have been 4 probably a booklet or a slide deck on the procedure. 5 Of course, there's the IFU.</p> <p>6 And primarily it's the literature, my 7 friends. I don't rely as much on slide decks, IFUs, 8 as I do on these other sources of information.</p> <p>9 Q. Okay. But you do look at the information, I think 10 you previously testified that you look at the 11 information the medical device manufacturer would 12 give you prior to implanting their product, correct?</p> <p>13 A. Yeah. It may not be important to me, but, yeah, I 14 look at it.</p> <p>15 Q. And you would expect that Ethicon would fully 16 disclose to you all of the risks that it knew of, it 17 knew were associated with the TVT product, correct?</p> <p>18 MR. KOOPMANN: Object to form.</p> <p>19 THE WITNESS: As a surgeon who had done, 20 I don't know, a thousand slings before I did my 21 first TVT, I really don't need Ethicon telling me 22 the risks and complications of sling procedures. 23 They would have to tell me something that would not 24 commonly be known to me.</p>
<p style="text-align: right;">Page 47</p> <p>1 Lucente. I don't recall who were the major 2 publishers in that time period.</p> <p>3 Also at the meetings, the meetings are 4 very important for us. People come up, they give 5 their presentation, we're able to talk informally, 6 and that helps me quite a bit.</p> <p>7 Q. Okay. And did you receive information from Ethicon 8 prior to using the TVT?</p> <p>9 A. So what I would have done is I would have had to had 10 some training by Ethicon and/or some mentoring by 11 Ethicon before doing that. I would have gone to a 12 cadaver lab or would have gone to a surgeon's home 13 site and observed or done both.</p> <p>14 I apologize. I don't recall because it's 15 just been so long ago. But I recall doing all of 16 these things, cadaver labs, visiting surgeons, 17 watching them do them.</p> <p>18 I had done a lot of surgeries, so I was 19 pretty comfortable with these techniques. We use 20 trocars all the time when we do slings and other 21 things.</p> <p>22 Q. I'm asking you specifically, though, about Ethicon.</p> <p>23 A. Okay.</p> <p>24 Q. Okay. What information did you receive from Ethicon</p>	<p style="text-align: right;">Page 49</p> <p>1 BY MS. FITZPATRICK:</p> <p>2 Q. So a medical device -- so your testimony is a 3 medical device manufacturer does not have a 4 responsibility to tell physicians who are using its 5 product of the risks it knows are associated with 6 the product, is that what you're saying? There's no 7 obligation to do that?</p> <p>8 MR. KOOPMANN: Object to form.</p> <p>9 BY MS. FITZPATRICK:</p> <p>10 Q. I mean, they either have to tell you or they don't. 11 I just want to know which one you think it is.</p> <p>12 A. I think that they should tell us risks that would 13 not commonly be known to surgeons and that would be 14 unique to their device.</p> <p>15 Q. And you realize, Doctor, that not everybody who's 16 used a TVT has the same level of experience 17 implanting a thousand slings before they started 18 using a TVT device, correct?</p> <p>19 A. Probably.</p> <p>20 Q. And not every physician has the opportunity that you 21 do to go to all of these meetings and to meet with 22 all of your colleagues, correct?</p> <p>23 A. I'm not sure. Probably.</p> <p>24 Q. Okay. And you realize that where you practice and</p>

<p style="text-align: right;">Page 54</p> <p>1 the mid-urethral sling which is why the whole world 2 went to mid-urethral slings. 3 Q. Your hands are not everybody's hands, though, 4 correct? 5 A. Yes. 6 Q. And you recognize there are reported complications 7 that are unique to mesh slings that are not reported 8 in association with fascial slings, correct? 9 A. Those complications in my mind would be entirely 10 mesh related -- 11 Q. Okay. 12 A. -- and nothing else. 13 Q. And nobody -- not everybody has the same results 14 with polypropylene mid-urethral slings that you 15 have, correct? 16 A. Interestingly, as I look at the meta-analyses, the 17 data that I see is pretty consistent with my 18 experience. 19 Q. Okay. So you're pretty middle of the road, you get 20 the same results that other people do, is that 21 right? 22 A. Yeah. I would say that my results are similar to 23 what we see in the very large studies. 24 Q. Okay.</p>	<p style="text-align: right;">Page 56</p> <p>1 you do a year? 2 A. I'm not sure. A hundred. I don't know. Two 3 hundred. I'm not sure. 4 Q. Okay. Let's try to just break it down. How many 5 roughly percentage-wise if you can give me, how many 6 of the slings that you implant are the Abbrevio? 7 A. So my obturator approach, it's about ninety percent 8 of what I do. 9 Q. Okay. And about how many are the retropubic? 10 A. The remaining. Well, maybe nine percent to probably 11 one percent, maybe two percent fascial slings at 12 this time. 13 Q. Okay. And you agree with me the fascial sling is 14 within the standard of care even though it's not 15 your preferred surgical intervention, correct? 16 A. Yes. 17 Q. All right. So you offered a report on the TVT-O 18 specifically. 19 What are the differences between the 20 TVT-O and the Abbrevio product that you use? 21 A. So, first of all, let me just qualify that. In our 22 field we tend to -- TVT-O has become kind of a very 23 generic term. So sometimes I'll say TVT-O and what 24 I mean is obturator sling.</p>
<p style="text-align: right;">Page 55</p> <p>1 A. Some, you know, some differences, but -- 2 Q. Well, we will -- I want to look at some of those in 3 a little bit. 4 A. Okay. 5 Q. But before we get there, so you do fascial slings. 6 What retropubic slings do you use? 7 A. I use the TVT Exact. 8 Q. And what obturator slings do you use? 9 A. I use the Abbrevio. 10 Q. And the Abbrevio is a different or a modified version 11 of the TVT-O, is that right? 12 A. I look at the Abbrevio as an upgraded product. When 13 you come out, when you have experience and you have 14 time to reflect and think about the technologies, 15 the next generation is often slightly improved over 16 the first. So -- 17 Q. Is the Abbrevio an updated improvement over the 18 traditional TVT-O in your opinion? 19 A. I like the Abbrevio. It's my sling of choice now for 20 many, many reasons. In fact, it's my primary sling 21 of choice. I prefer that over retropubic slings. 22 But if the Abbrevio were off the market 23 tomorrow and all we had was TVT-O, I would use that. 24 Q. Okay. Well, let's say how many sling surgeries do</p>	<p style="text-align: right;">Page 57</p> <p>1 Q. Okay. 2 A. Okay. Just to qualify that. 3 Q. Okay. That's fair enough. 4 I want to talk very specifically about 5 not TOT, not the transobturator slings generally but 6 the Ethicon TVT-O device. 7 A. Okay. 8 Q. Okay. So the difference between the Ethicon TVT-O 9 device and the Ethicon Abbrevio device. 10 A. Yes. 11 Q. What are the differences? 12 A. The differences are first that the Abbrevios or 13 Abbrevios are all laser-cut mesh. 14 That's not as important to me clinically. 15 The most important thing to me clinically is it's a 16 shorter length. 17 Q. And having a shorter length, it doesn't go as far 18 out into the groin and thigh, correct, as the 19 traditional TVT-O? 20 A. Correct. 21 Q. Okay. And what in your opinion is the advantage of 22 having the shorter length of the Abbrevio versus the 23 TVT-O? 24 A. That's actually a really important issue, and the</p>

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<p>1 concern is groin pain, and clinically, I see this</p> <p>2 very infrequently but I still worry about it because</p> <p>3 this is a quality of life procedure, and I'm trying</p> <p>4 to make sure my patients are happy when we're done.</p> <p>5 And although I see, again, I would say</p> <p>6 extremely infrequent groin pain that lasts more than</p> <p>7 a few weeks, if I can try and minimize that by</p> <p>8 having a mesh band that does not go through the</p> <p>9 adductor muscle group, then that's intuitive to me.</p> <p>10 Q. Do you believe that the -- so your primary reason is</p> <p>11 you believe that there's a decrease in the chance of</p> <p>12 a long-term groin pain in a woman.</p> <p>13 Is that sort of my layperson's</p> <p>14 interpretation of what you're saying?</p> <p>15 A. So it was really an intellectual decision because</p> <p>16 clinically I was not seeing problems with groin</p> <p>17 pain. I mean, it was very, very infrequent. We</p> <p>18 talk about it in the literature, we see it in</p> <p>19 conferences, and it had my attention. The numbers</p> <p>20 are very low, but I worry about it. You worry.</p> <p>21 That's what I do.</p> <p>22 So when the shorter mesh came out, I</p> <p>23 looked at it, I said this is logical. Maybe if I</p> <p>24 have one patient in a thousand who has that</p>	<p>1 stress incontinence, and if that's the case, those</p> <p>2 are the three procedures we discuss.</p> <p>3 Q. Okay. And why do you use the TVT Exact over just</p> <p>4 the TVT-O?</p> <p>5 A. There's two scenarios where I might do that. Number</p> <p>6 one is if the patient has had a prior mid-urethral</p> <p>7 sling, there's some data, not great data, but</p> <p>8 there's some data that argues that a retropubic</p> <p>9 vector improves overcomes over the obturator vector</p> <p>10 in that specific subgroup.</p> <p>11 The second reason would be if the patient</p> <p>12 has dyspareunia or pelvic pain, and what I would do</p> <p>13 in that patient is on exam, I would feel their</p> <p>14 pelvic floor muscles, and if they have any evidence</p> <p>15 of pelvic floor muscle pain or discomfort, I would</p> <p>16 not use an obturator sling in that patient.</p> <p>17 Q. Okay. I think I misspoke. I was going to ask you</p> <p>18 that question too, so you already gave me that.</p> <p>19 Why would you use a TVT Exact over the</p> <p>20 TVT-R?</p> <p>21 A. I thought you said TVT-O.</p> <p>22 Q. I apparently did. I just misspoke.</p> <p>23 A. Okay.</p> <p>24 Q. So --</p>
Page 59	Page 61
<p>1 complication and I can prevent that one patient in a</p> <p>2 thousand from having it, I'd like to do that.</p> <p>3 Q. Okay. And is there anything else that recommends</p> <p>4 the Abbrevio over the TVT-O device to you?</p> <p>5 A. No.</p> <p>6 Q. Okay. Do you even implant the TVT-O at all, or do</p> <p>7 you just use the Abbrevio at this point?</p> <p>8 A. At this point I use the Abbrevio. If we don't have</p> <p>9 it, I'll use a TVT-O.</p> <p>10 Q. Okay. And when did you change from the TVT-O to the</p> <p>11 Abbrevio?</p> <p>12 A. I'm sorry. I'm not sure. A few years ago, a couple</p> <p>13 few years ago.</p> <p>14 Q. Okay. Now, so a woman comes in to see you and she</p> <p>15 needs a surgical intervention for stress urinary</p> <p>16 incontinence. You offer her three potential</p> <p>17 procedures, the Abbrevio, the TVT Exact, and the</p> <p>18 fascial sling.</p> <p>19 Those are your three options, is that</p> <p>20 right?</p> <p>21 A. Well, there's another surgical option that's</p> <p>22 periurethral injection.</p> <p>23 But we're -- I'm assuming that we're</p> <p>24 talking about a patient with simple, straightforward</p>	<p>1 A. TVT-R. I like the curve of the trocar and the hand</p> <p>2 movement, but that's personal preference. I've used</p> <p>3 them both.</p> <p>4 Some people really like the big trocar.</p> <p>5 They feel they can guide it easier and have more</p> <p>6 control over it. I happen to like the other trocar.</p> <p>7 It's just personal preference.</p> <p>8 Q. Okay. And so let's go back to the question that I</p> <p>9 asked and you answered. The primary reason -- I</p> <p>10 just want to get this in my mind. A woman comes in</p> <p>11 to you for a surgical intervention, okay?</p> <p>12 Is your -- generally your first</p> <p>13 recommendation that they have the Abbrevio sling, and</p> <p>14 you only go to the TVT Exact or the fascial sling if</p> <p>15 there's some kind of reason why you don't think that</p> <p>16 the Abbrevio is particularly suited for that woman,</p> <p>17 is that right?</p> <p>18 A. Yeah. There are a few things that I look at, but if</p> <p>19 there are none of the risk factors that I am</p> <p>20 considering, my first choice is an inside-out</p> <p>21 obturator sling which is the Abbrevio.</p> <p>22 Q. Okay. And the risk factors that you discussed were</p> <p>23 women who already have some type of pelvic floor or</p> <p>24 pelvic muscle discomfort or dyspareunia, is that</p>

<p style="text-align: right;">Page 62</p> <p>1 right?</p> <p>2 A. Yes.</p> <p>3 Q. And is there any other risk factor that you can</p> <p>4 identify for me that would have you recommend the</p> <p>5 Exact over the Abbrevio?</p> <p>6 A. Yes. That is in a patient who will have had prior</p> <p>7 mid-urethral sling, and those patients, again,</p> <p>8 there's some literature, mostly case series and</p> <p>9 things, not great, no Level I evidence, that argues</p> <p>10 that the retropubic vector in those patients may be</p> <p>11 better than the obturator vector, but studies like</p> <p>12 that, you know, that are not large they've been</p> <p>13 proven wrong before.</p> <p>14 For example, you know, when we looked at</p> <p>15 the retropubic versus the obturator sling, one of</p> <p>16 the big issues was if a patient has ISD, if they</p> <p>17 have severe leakage, is the retropubic sling tighter</p> <p>18 or not than the obturator, and I have to say I</p> <p>19 thought that it was, and I was in a group that</p> <p>20 thought that it was. There's papers that said it</p> <p>21 was, some papers said that it wasn't.</p> <p>22 So when we did our large six hundred</p> <p>23 patient prospective randomized trial and then we</p> <p>24 evaluated those patients according to leak point</p>	<p style="text-align: right;">Page 64</p> <p>1 A. Nothing that I can think of right now.</p> <p>2 Q. Okay. And then you also do a very small number of</p> <p>3 fascial slings, is that correct?</p> <p>4 A. Yes.</p> <p>5 Q. Are those ever -- do you ever recommend a fascial</p> <p>6 sling to a patient?</p> <p>7 A. I do.</p> <p>8 Q. Okay. And in what candidates would you recommend a</p> <p>9 fascial sling or a polypropylene mid-urethral sling?</p> <p>10 A. So the brilliant thing about the mid-urethral sling</p> <p>11 is that it's tension free. That was just a critical</p> <p>12 advance, and it's changed. It's been the single</p> <p>13 most important thing that has improved the side</p> <p>14 effect profile of these procedures.</p> <p>15 The fascial slings are placed at the</p> <p>16 bladder neck, not the mid-urethra, and historically</p> <p>17 they have been what we call compressive and which</p> <p>18 means obstructive which means that the patients have</p> <p>19 higher urgency rates and higher UTI rates, all of</p> <p>20 which are proven in the literature.</p> <p>21 So when I have a patient whose urethra is</p> <p>22 mobile, it's moving, then I can put a mid-urethral</p> <p>23 sling in them. The urethra moves, hits the sling,</p> <p>24 and it works. Dynamic kinking is what we would call</p>
<p style="text-align: right;">Page 63</p> <p>1 pressures which is a severity of urethral</p> <p>2 dysfunction, we found that both slings worked</p> <p>3 exactly the same.</p> <p>4 So that was the first really big study to</p> <p>5 inform us as a field that the obturator sling works</p> <p>6 as well as the retropubic sling in patients with</p> <p>7 severe dysfunction, so that's not something that I</p> <p>8 use.</p> <p>9 Interestingly, when I go to the meetings,</p> <p>10 everybody at the meetings will say retropubic slings</p> <p>11 are tighter, and that's because they're not reading</p> <p>12 the literature.</p> <p>13 Q. Okay. So I want to go back to my question.</p> <p>14 Dyspareunia, pelvic floor muscle dysfunction, that's</p> <p>15 one risk factor that would have you recommend the</p> <p>16 TVT-R to a small subgroup of your -- subpopulation</p> <p>17 of your patients, right?</p> <p>18 A. So the retropubic sling instead of an obturator?</p> <p>19 Q. Right. Prior mid-urethral sling, you would go to a</p> <p>20 retropubic over the obturator in that case, correct?</p> <p>21 A. For now until that's proven to be wrong.</p> <p>22 Q. Okay. Anything else, any other risk factors that</p> <p>23 would have you recommend to a woman that she have a</p> <p>24 retropubic as opposed to an Abbrevio device?</p>	<p style="text-align: right;">Page 65</p> <p>1 that in the literature.</p> <p>2 But when a patient is scarred and the</p> <p>3 urethra is not moving, then I have to take my sling</p> <p>4 and I have to take my sling to the urethra and</p> <p>5 compress it, and that, I'm going to place fascia</p> <p>6 because we don't put mesh under tension. Mesh under</p> <p>7 tension could erode into the urethra.</p> <p>8 So a fascial sling is typically under a</p> <p>9 little bit more compression, and what we know is</p> <p>10 commonly we're obstructing these patients which</p> <p>11 leads, again, to a whole another set of side effects</p> <p>12 which sometimes for a patient is more bothersome</p> <p>13 than their leakage in the first place. So it gets</p> <p>14 to be a very tricky, tricky population.</p> <p>15 Q. Okay. Now, regardless of what procedure you're</p> <p>16 doing, the Abbrevio, the TVT Exact, or the fascial</p> <p>17 sling, you discuss the options with your patients,</p> <p>18 correct?</p> <p>19 A. Yes.</p> <p>20 Q. And you give them informed consent, correct?</p> <p>21 A. Yes.</p> <p>22 Q. And what -- let's start with the Abbrevio. What are</p> <p>23 the risks that you tell your patients about that can</p> <p>24 be associated with the use of the Abbrevio device?</p>

<p style="text-align: right;">Page 90</p> <p>1 That is unique to this.</p> <p>2 Prolene may potentiate existing</p> <p>3 infection. The next one's on obstruction. We know</p> <p>4 that. Acute or chronic pain, any surgery we do can</p> <p>5 do that. Voiding dysfunction, that goes up with the</p> <p>6 bullet above. I don't know why they split that into</p> <p>7 two different bullets. Pain with intercourse, we</p> <p>8 know about that. Neuromuscular problems, again,</p> <p>9 same idea. We know about that. Recurrence,</p> <p>10 bleeding, revisions, and then the last one, a</p> <p>11 permanent implant that integrates into the tissue.</p> <p>12 So that is unique to this when they talk about mesh.</p> <p>13 However, if I have to go in and take the</p> <p>14 Burch sutures out that eroded into a bladder or</p> <p>15 fascial sling is out that is obstructing, that can</p> <p>16 be a very difficult dissection as well.</p> <p>17 Q. Let me ask you based on these adverse reactions that</p> <p>18 you just reviewed, is there any reason that you know</p> <p>19 of from your medical and clinical point of view, any</p> <p>20 reason that those adverse reactions that are</p> <p>21 identified in the post 2015 IFU could not have been</p> <p>22 included in the pre-2015 IFU?</p> <p>23 MR. KOOPMANN: Object to form,</p> <p>24 foundation.</p>	<p style="text-align: right;">Page 92</p> <p>1 BY MS. FITZPATRICK:</p> <p>2 Q. I'm not asking you that. I'm asking, you are a</p> <p>3 clinician and a medical doctor.</p> <p>4 A. Yeah.</p> <p>5 Q. I'm not asking you -- there's no way you can know</p> <p>6 what Ethicon was thinking.</p> <p>7 A. Right.</p> <p>8 Q. I'm asking from a purely medical point of view, what</p> <p>9 was known in the medical community about potential</p> <p>10 adverse reactions to the TVT device. Is there any</p> <p>11 reason based on that body of knowledge that you have</p> <p>12 that any of these adverse reactions could not have</p> <p>13 been identified in an IFU prior to 2015?</p> <p>14 A. So, I apologize, but, you know, your question could</p> <p>15 not have -- I'm getting thrown off by that.</p> <p>16 Q. Is there anything new here that physicians didn't</p> <p>17 know prior to 2015?</p> <p>18 A. No. In fact, I would argue that we could probably</p> <p>19 still have the same four bullet points here, and I</p> <p>20 would still be comfortable with that.</p> <p>21 Q. Or we could also argue that each of these adverse</p> <p>22 reactions could have made it into the earlier IFU</p> <p>23 because they were known as potential complications</p> <p>24 and adverse events with the TVT, right? It could</p>
<p style="text-align: right;">Page 91</p> <p>1 THE WITNESS: So my understanding when</p> <p>2 you look at both federal regulations and guidelines</p> <p>3 on IFUs, it has to be something that is unique, that</p> <p>4 is unique to the procedure and not commonly known.</p> <p>5 And that's kind of where the whole</p> <p>6 argument is here is that these things are commonly</p> <p>7 known. The only thing that is unique here are the</p> <p>8 ones that specifically deal with mesh. We know</p> <p>9 removing it's hard, but mesh exposure is unique to</p> <p>10 these products, yes.</p> <p>11 BY MS. FITZPATRICK:</p> <p>12 Q. It's not my question.</p> <p>13 A. I'm sorry.</p> <p>14 Q. Is there any reason based on your medical</p> <p>15 knowledge and your clinical knowledge, is there</p> <p>16 any reason why any or all of these adverse</p> <p>17 reactions that are identified in the 2015 IFU</p> <p>18 could not have been listed in the pre-2015 IFU?</p> <p>19 Are these new things that people didn't know about</p> <p>20 until 2015?</p> <p>21 MR. KOOPMANN: Object to form.</p> <p>22 THE WITNESS: So I can't really comment</p> <p>23 on what the people at Ethicon were thinking when</p> <p>24 they --</p>	<p style="text-align: right;">Page 93</p> <p>1 have gone either way?</p> <p>2 A. But this is just, I mean, I don't know who selected</p> <p>3 these things. We don't have blood clot on here. We</p> <p>4 could have gotten into blood clot.</p> <p>5 Q. We could go down to the other adverse reactions as</p> <p>6 well.</p> <p>7 A. Yeah.</p> <p>8 Q. I'm just asking you, Doctor, I don't care which IFU</p> <p>9 you like better.</p> <p>10 A. Okay.</p> <p>11 Q. I'm just asking you, is there any reason that you</p> <p>12 know of based on your knowledge of the medical and</p> <p>13 scientific literature that what Ethicon chose to put</p> <p>14 into its IFU in 2015 could not have been</p> <p>15 incorporated into an earlier version of the IFU</p> <p>16 based on medical and scientific knowledge? That's</p> <p>17 all.</p> <p>18 A. You know, it's the could not. It's like a double</p> <p>19 negative.</p> <p>20 So, so are you saying that Ethicon could</p> <p>21 have put these in earlier IFUs, is that a simpler</p> <p>22 way of saying it?</p> <p>23 Q. Could Ethicon have put these adverse events into</p> <p>24 early IFUs?</p>

<p style="text-align: right;">Page 126</p> <p>1 weight? Do you recall that?</p> <p>2 A. So there's the Amid study which is the original</p> <p>3 study on pore size, Type I, Type II, Type III, Type</p> <p>4 IV.</p> <p>5 I also looked at Pam Moalli's paper from</p> <p>6 2008 --</p> <p>7 Q. And is it your --</p> <p>8 A. -- and many other articles and documents looking at</p> <p>9 pore size.</p> <p>10 Q. That Moalli paper that you just referenced, that</p> <p>11 contains a table in it that lists the density and</p> <p>12 pore size of various incontinence slings?</p> <p>13 A. Yes.</p> <p>14 Q. And that's something you've reviewed?</p> <p>15 A. Yes.</p> <p>16 Q. You testified earlier today that you've explanted</p> <p>17 some polypropylene mesh slings or portions of some</p> <p>18 polypropylene mesh slings, is that right?</p> <p>19 A. That's correct.</p> <p>20 Q. And when you had occasion to do that, did you look</p> <p>21 at the mesh that you explanted?</p> <p>22 A. Yes.</p> <p>23 Q. In that gross examination of the mesh, did you</p> <p>24 observe any degradation?</p>	<p style="text-align: right;">Page 128</p> <p>1 TVT-O devices was safe and effective when you</p> <p>2 started using the TVT-O?</p> <p>3 A. Yeah. So when the TVT-O came out, the idea was that</p> <p>4 it's the exact same mesh, it's the exact same</p> <p>5 location, it's just a different way of getting it</p> <p>6 there, and we were very comfortable with that.</p> <p>7 Q. Do you offer the Burch procedure as a stress urinary</p> <p>8 incontinence treatment to your patients today?</p> <p>9 A. I do not.</p> <p>10 Q. Why not?</p> <p>11 A. So we did a large prospective randomized trial on</p> <p>12 Burch, and it just, it's not, it's not durable.</p> <p>13 It's not effective. So when I would do it before,</p> <p>14 it was only when we were in the abdomen, and it was</p> <p>15 there, it was easy, we were in the abdomen, we would</p> <p>16 do a Burch.</p> <p>17 But now when they're in the abdomen, if</p> <p>18 they need an anti-incontinence procedure, I'd do a</p> <p>19 mid-urethral sling. So I'll let them finish in the</p> <p>20 belly, close, then I'll go vaginally and I will do</p> <p>21 mid-urethral sling because they're more effective,</p> <p>22 and I think that they have a better safety profile.</p> <p>23 Q. Have you actually seen lower rates of groin pain or</p> <p>24 leg pain with your TVT Abbrevio patients than you did</p>
<p style="text-align: right;">Page 127</p> <p>1 A. It looked normal to me.</p> <p>2 Q. And does your outcomes with your patients in whom</p> <p>3 you've implanted a mid-urethral polypropylene sling</p> <p>4 like the TVT or TVT-O inform your opinion about</p> <p>5 whether or not the mesh in those slings degrades?</p> <p>6 A. Yeah. I find it just, I find it so interesting to</p> <p>7 read these internal documents on mesh degradation</p> <p>8 because it was a surprise to me and because</p> <p>9 clinically I just have not seen any evidence of this</p> <p>10 at all.</p> <p>11 We have long-term studies looking at</p> <p>12 patients looking at their clinical outcome, clinical</p> <p>13 outcome meaning continued improvement in symptoms</p> <p>14 but also meaning lack of progression of scar tissue,</p> <p>15 pain, discomfort, et cetera. So I just don't see</p> <p>16 any clinical evidence that this is an issue.</p> <p>17 Q. There was some discussion earlier about what</p> <p>18 literature you relied on at the time that you</p> <p>19 started to use the TVT and at the time that you</p> <p>20 started to use the TVT-O.</p> <p>21 Do you recall that generally?</p> <p>22 A. Yes, yes.</p> <p>23 Q. Did you also rely on the TVT literature that existed</p> <p>24 as something that made you feel comfortable that the</p>	<p style="text-align: right;">Page 129</p> <p>1 with your TVT-O patients?</p> <p>2 A. No. I really haven't. I haven't formally studied</p> <p>3 it, but anecdotally in my, just evaluation of my</p> <p>4 patients, I have not seen that. We do look at these</p> <p>5 patients when we do our trials.</p> <p>6 I don't have a prospective sling database</p> <p>7 but I have retrospective sling databases, and we</p> <p>8 have not seen a difference.</p> <p>9 Q. Does the TVT Abbrevio use the exact same mesh as the</p> <p>10 TVT-O?</p> <p>11 A. No. The Abbrevio is a laser-cut mesh.</p> <p>12 Q. But apart from the cutting technique, is it the same</p> <p>13 mesh?</p> <p>14 A. Yes, it's the same mesh.</p> <p>15 Q. And there's laser-cut TVT-O mesh, correct?</p> <p>16 A. There is, that's correct.</p> <p>17 Q. In addition to mechanically cut TVT-O devices?</p> <p>18 A. That's correct.</p> <p>19 Q. But the mesh in the TVT Abbrevio and the TVT-O is the</p> <p>20 same polypropylene?</p> <p>21 A. Yes, it's the same weave, monofilament.</p> <p>22 Q. It's the same weight or density?</p> <p>23 A. Same weight, same pore size. It's a hundred grams</p> <p>24 per liter squared.</p>

<p style="text-align: right;">Page 130</p> <p>1 Q. Does the mesh used in the two devices lay under the 2 urethra at the same spot? 3 A. It does. We do that on purpose. 4 Q. Does the TVT Exact use the exact same mesh as the 5 TVT with the exception of the cutting technique? 6 A. Yes, yes, it is. 7 Q. But, again, with the TVT there's also laser-cut mesh 8 available, is that your understanding? 9 A. That's correct. 10 Q. And is the TVT Exact mesh the same weight and pore 11 size as the TVT mechanically cut mesh? 12 A. Yes, it is. 13 Q. And that mesh lays under the urethra at the same 14 place? 15 A. Yes. 16 Q. I'm going to ask you a couple of follow-up questions 17 about Exhibit 11 and 12. 11 is the TVT IFU before 18 2015, and 12 is the TVT IFU before 2015. 19 A. Okay. I have them both. 20 Q. Which one do you have in front of you right now that 21 you're looking at? 22 A. I have the TVT-O one. 23 Q. Okay. So if you look at the TVT-O marked as 24 Exhibit 12, there was some discussion earlier about</p>	<p style="text-align: right;">Page 132</p> <p>1 However, I did not review that carefully 2 enough before talking about that this morning, and 3 it does clearly say that. 4 BY MR. KOOPMANN: 5 Q. And the TVT-O IFU on the first page, one of the 6 things it says in a paragraph at the top of the 7 first substantive page I'll call it that says 8 English at the top, it says: The device should be 9 used only by physicians trained in the surgical 10 treatment of stress urinary incontinence and 11 specifically in implanting the Gynecare TVT 12 obturator device, is that correct? 13 A. Yes, that's correct. 14 Q. And if you go to the TVT IFU marked as Exhibit 11, 15 it also says: The device should be used only by 16 physicians trained in the surgical treatment of 17 stress urinary incontinence and specifically in 18 implanting the Gynecare TVT device, is that correct? 19 A. Yes, that's correct. And really, all these 20 decisions are not -- these decisions are all made by 21 the local hospitals, universities, et cetera, who do 22 privileging, chairman of the department. That's how 23 we decide who can implant and who cannot implant. 24 It's a local decision made by the administrations</p>
<p style="text-align: right;">Page 131</p> <p>1 the adverse reaction section. 2 Do you recall that? 3 A. Yes. 4 Q. Right above the adverse reaction section, there's a 5 section that says warnings and precautions, is that 6 right? 7 A. Yes. 8 Q. And if you look at the fifth bullet point from the 9 bottom of that list of warnings and precautions, it 10 says: Transient leg pain lasting twenty-four to 11 forty-eight hours may occur and can usually be 12 managed with mild analgesics, is that correct? 13 A. Correct, yes. 14 Q. And then if you look at the Exhibit 11 which is the 15 TVT IFU, before 2015, you don't see that same 16 notation of transient leg pain, do you? 17 A. That's correct. 18 Q. So in that respect, would you agree that these TVT 19 and TVT-O IFUs before 2015 do set forth a different 20 risk profile? 21 MS. FITZPATRICK: Objection. 22 THE WITNESS: Yeah. I apologize for 23 that. I will tell you that the print is so small, I 24 can hardly see it even with my glasses on.</p>	<p style="text-align: right;">Page 133</p> <p>1 and departments at the local hospitals. 2 Q. Is the fact that data can change over time one of 3 the reasons surgeons continue to do studies and 4 systematic reviews and meta-analyses? 5 A. Yeah, and I alluded to that in talking about how the 6 literature develops, and we learn more and more 7 things as time goes on. 8 Q. And is a continuing review of the literature 9 something that surgeons do as part of their 10 practice? 11 A. It's what we constantly do. In fact, in programs 12 like ours, we have a journal club every month 13 specifically to look at the new literature to keep 14 ourselves updated. 15 Q. Can a risk profile of a device change over time? 16 A. Absolutely, especially as we learn more about it and 17 we're informed. 18 Q. The additional adverse reactions and other adverse 19 reactions that counsel went over earlier with you in 20 the 2015 IFUs for the TVT and TVT-O which have been 21 marked as Exhibits 13 and 14 respectively, in your 22 opinion was there any reason that those additional 23 adverse reactions that were not seen in prior 24 versions of the IFU needed to be included in the</p>

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1 products versus AMS products, and what you told me,
2 I did not do one at my institution but I
3 participated in the overall study.
4 A. Yeah. So, so we did not do it at Beaumont, you're
5 right. I participated in the study that pulled the
6 data and looked at it on the national level.
7 Q. Those weren't your patients, right?
8 A. Some of them were but not all of them, no.
9 Q. You didn't do it at Beaumont?
10 A. We did not do a study at Beaumont where we compared
11 Ethicon versus AMS or somebody else.
12 Q. And those are your patients who you haven't done a
13 study in your patients at Beaumont that compared
14 Ethicon to another manufacturer, right?
15 A. But what we did is we participated in the study that
16 compared AMS and Ethicon on a national level.
17 Q. Okay.
18 A. But not on a local level.
19 MS. FITZPATRICK: That's all that I have.
20 Thank you.
21
22 (Deposition concluded at 12:50 p.m.)
23
24

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1 STATE OF MICHIGAN)
)SS.
2 COUNTY OF LIVINGSTON)
3 CERTIFICATE OF NOTARY PUBLIC
4 I certify that this transcript
5 is a complete, true, and correct record of the
6 testimony of the deponent to the best of my ability
7 taken on Thursday, July 21, 2016.
8 I also certify that prior to
9 taking this deposition, the witness was duly sworn
10 by me to tell the truth.
11 I also certify that I am not a
12 relative or employee of a party, or a relative or
13 employee of an attorney for a party, have a contract
14 with a party, or am financially interested in the
15 action.
16
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18
19
20
21
22 Cheryl McDowell, CSR-2662, RPR
23 Notary Public, Livingston County
24 State of Michigan
Commission Expires September 13, 2019